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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,779	12/10/1999	MARTIN LATTERICH	1211.001US1	9268

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EXAMINER

DAVIS, KATHARINE F

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/26/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/458,779

Applicant(s)

LATTERICH ET AL.

Examiner

Katharine F. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-12, 14-23, 25-27, 29-34 and 36-46 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 3-12, 14-23, 25-27, 29-34 and 36-46 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☒ Other: Appendix B

### **DETAILED ACTION**

This Office Action is in response to the Amendment filed on January 7, 2002. Claims 1, 2, 13, 24, 28 and 35 have been cancelled. Claims 3-12, 14-23, 25-27, 29-34 and 36-46 are pending in the instant application.

The objection to claim 12 and the rejections of claims 31-34 and 44 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments to the claims and the remarks presented by the Applicants in the January 7, 2002 Amendment. The rejection of claims 8, 9, 10, 19-21, 27, 30-34, 37-43 and 46 (method claims and claims drawn to an expression vector encoding a heterologous protein) under 35 U.S.C. 102(a) has been withdrawn in view of the remarks presented by the Applicants in the January 7, 2002 Amendment.

The Amendment filed on January 7, 2002 was subjected to the United States Postal Service irradiation process, see attached Appendix B.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-12, 14-23, 25-27, 29-34 and 36-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 3, 14, 25, 31, 33, 36 and 37 have been amended to include the phrase “greater than 36% sequence identity with SEQ ID NO:2”. Applicants cite page 11, lines 1-11 of the instant specification as support for the addition of this phrase to the claims (page 7 of the Amendment filed January 7, 2002). This citation has been carefully considered but is not deemed to support the addition of the above-referenced phrase in claims 3, 14, 25, 31, 33, 36 and 37. The citation at page 11 of the instant specification states that SEQ ID NOS:1 and 2 are unique sequences in the yeast *Saccharomyces cerevisiae* and further states that by BLAST analysis homologous sequences have been identified in *Saccharomyces pombe*, the nematode *Caenorhabditis elegans*, and the plant *Arabidopsis*. These homologous regions are open reading frames in the sequenced genome of these organisms. Vff2p has 36% sequence identity with an open reading frame in *Saccharomyces pombe*. The instant specification further indicates that these ORFS had not been studied at the time of filing (see page 11, line 6). Since these ORFS have not been studied it is not known if the ORF from *Saccharomyces pombe* actually encodes a Vff2 protein nor is it known if the protein encoded by this ORF increases yeast cell growth or protein secretion. Therefore the phrase “greater than 36% sequence identity with SEQ ID NO:2” as added to claims 3, 14, 25, 31, 33, 36 and 37 is considered to be **new matter** and must be removed from the claims.

Claims 3-12, 14-23, 25-27, 29-34, 36-42 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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It is noted that this rejection was (in the previous Office Action mailed on July 5, 2001) and is currently based upon the "Written Description" requirement published in the Federal Register at Volume 66, Number 4, pages 1099-1111. The citation of the "Written Description" requirement (published in the Federal Register at Volume 64, Number 244, pages 71427-71440) in the immediately previous Office Action was inadvertent, however it is noted that this citation was current in the previous Office Action mailed on December 15, 2000.

Applicants' arguments presented on pages 8 and 9 of the Amendment filed on January 7, 2002 have been carefully considered but have not been found to be persuasive. The term "variants" has been replaced with the phrase "proteins with greater than 36% sequence identity to SEQ ID NO:2". The instant claims are now drawn to polynucleotides encoding Vff2 proteins with greater than 36% sequence identity with SEQ ID NO:2. These are genus claims encompassing any protein and/or polynucleotide encoding said protein from any organism having greater than 36% sequence identity to the claimed SEQ ID NO:2. The instant specification discloses the nucleic acid sequence and the protein sequence of Vff2 from the yeast *Saccharomyces cerevisiae* as shown in the Sequence Listing and the Examples. The disclosure of one example (Vff2 from the yeast *Saccharomyces cerevisiae*) is not deemed to be descriptive of the complete structure of a representative number of species (any protein and/or polynucleotide encoding said protein from any organism having greater than 36% sequence identity to the claimed SEQ ID NO:2) encompassed by the claims. Applicants assert that the phrase "sequences with greater than 36% sequence identity to the claimed SEQ ID NO:2" distinctly determines the structural boundaries of the invention and applicants additionally assert that the claims require the encoded Vff2 protein to increase yeast cell growth or protein secretion thereby also

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specifying the functional boundaries of the invention. However Applicants have not shown a correlation between structure and function. The sequence from the yeast *Saccharomyces pombe* was demonstrated by BLAST analysis to have 36% sequence identity with the claimed SEQ ID NO:2 but the sequence from *S. pombe* was not shown to actually increase yeast cell growth or protein secretion, thus showing no connection between structure and function. Additionally, there is no disclosure of the specific protein and/or nucleic acid sequences necessary for activity of Vff2p in the cellular secretory pathway. According to the teachings of the instant specification the yeast Vff2 protein is involved in the secretory pathway and/or involved in membrane fusion however there is no teaching of what domains and/or motifs are responsible for these functions of the Vff2 protein. Thus, a skilled artisan would be uncertain as to what structures may be associated with function. Therefore, the specification does not describe the claimed protein and nucleic acid sequences in such full, clear, concise and exact terms so as to indicate that the applicants had possession of these sequences (other than SEQ ID NOs:1 and 2) at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

For both the reasons above and the reasons made of record in the previous Office Actions mailed on July 5, 2001 and December 15, 2000 the rejection of claims 3-12, 14-23, 25-27, 29-34, 36-42 and 44-46 under 35 U.S.C. 112, first paragraph (Written Description) is maintained.

Claims 3-12, 14-23, 25-27, 29-34, 36-42 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide with a sequence of SEQ ID NO:1, a protein with a sequence of SEQ ID NO:2, and a host cell (*Saccharomyces cerevisiae*), does not reasonably provide enablement for polynucleotides and/or

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proteins other than SEQ ID NOs:1 and 2 or a host cell other than *Saccharomyces cerevisiae*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments presented on pages 9-11 of the Amendment filed on January 7, 2002 have been carefully considered but have not been found to be persuasive.

The area of the invention is still considered to be unpredictable. As discussed above in the Written Description rejection, Applicants assert that the instant invention claims defined structures that have specific functions, however no correlation of structure with function is shown. While the skilled artisan may be able to perform routine sequencing procedures such as a BLAST analysis to identify potential homologs having greater than 36% sequence identity with the claimed SEQ ID NO:2, homology by sequence alone does not predict function. Applicants provide no evidence that any potential homologs exhibit a similar function to that of the Vff2 protein.

The instant specification provides little direction or guidance to support the claimed invention in its full scope as the working examples relate only to Vff2 protein as SEQ ID NOS: 1 and 2 wherein the host cell is *Saccharomyces cerevisiae*. There are no examples provided wherein the Vff2 protein is encoded by a sequence with greater than 36% sequence identity to SEQ NO:2 nor is there an example wherein the host cell is any other than a *Saccharomyces cerevisiae* cell. Additionally, the instant specification is silent with regard to consideration of what domains and/or motifs are responsible for the function of the Vff2 protein. While the skilled artisan may be able to perform tests, such as the transformation of a yeast host cell with a

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vector encoding a Vff2 protein to assess the effect of the Vff2 protein on cell growth or protein secretion, one screening assay is not considered sufficient to identify Vff2 proteins. This identification would involve screening a large number of Vff2 sequences without any guidance as to where to begin screening which constitutes undue experimentation. Applicants assert that one of skill in the art understands that the claimed Vff2 proteins can function in any yeast species because the cellular structures and life cycles of yeast species are similar. As reiterated from above, no examples are provided in the instant specification wherein the host cell is any yeast cell other than a *Saccharomyces cerevisiae* cell. A protein cannot be assumed to function similarly in all yeast species because yeast species are similar in cellular structure and life cycle. In order to be certain of function and also to correlate structure with function large numbers of host cells of many different species of yeast would need to be transformed with large numbers of sequences having 36% sequence identity to the claimed SEQ ID NO:2. Applicants also assert that if one of skill in the art finds ambiguity or variation in function from one yeast species to another, one of skill in the art can adapt the inventive polynucleotide and proteins using the teachings of the instant specification so that they can be used in a variety of yeast host cells. How would one of skill in the art adapt these polynucleotides and/or proteins without undue experimentation? The instant specification provides only a general teaching on amino acid substitutions, deletions and/or insertions and is silent considering what domains and/or motifs are responsible for the function of the Vff2 protein. A skilled artisan would be uncertain as to which protein domains to target in order to obtain Vff2 that are functional in a variety of yeast species. The points raised in the above-discussion exemplify the undue experimentation which would be necessary to practice the claimed invention in its full scope.



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Additionally, Applicants refer to the court cases *In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) and *Hybritech Inc. v. Monoclonal Antibodies Inc.* 231 USPQ 81, 84 (Fed. Cir. 1986). Applicants cite these cases to provide support for their argument that a need to carry out extensive screening programs to identify and use functional Vff2 proteins in all species of yeast does **not** constitute undue experimentation. However, these cases both refer to the field of monoclonal antibody technology. Monoclonal antibody technology is a well-developed field (not considered to be analogous to the field of the instant invention) wherein it is standard practice to screen hybridomas to identify a desirable monoclonal antibody and one of skill in this art knows that the desired antibody could be obtained with sufficient screening. A Vff2 protein functional in a variety of yeast species (identified from those sequences with 36% sequence identity to claimed SEQ ID NO:2) may never be identified regardless of the amount of screening. The field of the instant invention is not as well-developed a field consequently there is not the same high expectation of success.

For both the reasons above and the reasons made of record in the previous Office Actions mailed on July 5, 2001, December 15, 2000 and April 10, 2000 the rejection of claims 3-12, 14-23, 25-27, 29-34, 36-42 and 44-46 under 35 U.S.C. 112, first paragraph (Scope of enablement) is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3-7, 11, 12, 14-18, 22, 23, 25, 26, 29, 36, 44 and 45 remain rejected under 35

U.S.C. 102(a) as being anticipated by Powell *et al.* (Mol. Biol. Cell 10(Suppl):298a, abstract No. 1727, November 1999, IDS reference). Applicants' arguments presented on pages 13 and 14 of the Amendment filed on January 7, 2002 have been carefully considered but have not been found to be persuasive. Applicants' argue that the abstract of Powell *et al.* does not disclose each and every element of the claims as is required by 35 U.S.C. 102(a) in order for a reference to be anticipatory. Powell *et al.* disclose a 32 kilodalton vesicle fusion factor 2 (Vff2) protein that is involved in membrane fusion. Powell *et al.* overexpress Vff2 protein in *Saccharomyces cerevisiae*. Powell *et al.* observe that the cells overexpressing Vff2p are larger, thus it is evident that Vff2p has some effect on cell growth. The sequences of Vff2p (both nucleotide and amino acid) are inherent properties to the molecules. Based on the disclosure of Powell *et al.* one of skill in the art would be able to overexpress the Vff2p in *Saccharomyces cerevisiae*. The instant specification discloses both a 32 kilodalton vesicle fusion factor 2 (Vff2) protein that is involved in membrane fusion and examples wherein Vff2 protein is overexpressed in *Saccharomyces cerevisiae*. The protein of Powell *et al.* appears to be the same protein that is claimed in the

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instant invention. In the absence of evidence to the contrary, both proteins must be assumed to be the same therefore Powell *et al.* does disclose each and every element of the rejected claims.

For both the reasons above and the reasons made of record in the previous Office Action mailed on July 5, 2001 the rejection of claims 3-7, 11, 12, 14-18, 22, 23, 25, 26, 29, 36, 44 and 45 under 35 U.S.C. 102(a) is maintained.

### *Conclusion*

Claims 3-12, 14-23, 25-27, 29-34 and 36-46 are rejected. Applicant's amendment necessitated the new ground(s) of rejection (new matter under 35 U.S.C. 112, first paragraph) presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

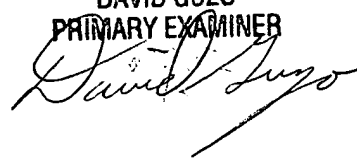
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195

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with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry of a general nature or any inquiry concerning the formalities of this application should be directed to Patent Analyst Tracey Johnson whose telephone number is (703) 305-2982.

Katharine F. Davis  
March 24, 2002

DAVID GUZO  
PRIMARY EXAMINER  


**Appendix B**

The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

**Mailroom Stamp Date**

January 7, 2002

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Certificate of Mailing Date**

November 5, 2001

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\_\_\_\_\_  
\_\_\_\_\_

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS  
ORIGINALLY FILED**

\_\_\_\_\_

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do not call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will not be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.